enclosed in payment of the fee therefor for a small entity (note small entity status of application and enclosed copy of previously filed small entity declaration). The Commissioner is hereby authorized to charge any additionally required fee for this three month extension of time or any other fee occasioned by this paper, or credit any overpayment in such fees, to Deposit Account No. 50-0320.

REMARKS

The Office Action dated January 6, 2000, issued a restriction requirement under 35 U.S.C. § 121 (*Office Action*, pgs. 2-3, points 2 – 3).

Reconsideration and withdrawl of the restriction requirement are respectfully requested in view of the remarks herewith.

TRAVERSAL OF THE RESTRICTION REQUIREMENT

The Office Action called for an election from among:

Group I: Claims 1 - 21, 29 –3 1, and 47 drawn to an isolated polypeptide, a pharmaceutical composition comprising said polypeptide, and a method of treatment using said polypeptide, classified in class 530 subclass 350.

Group II: Claims 34 - 43 drawn to a method of reconditioning a molecule by contacting said molecule with a polypeptide classified in class 435, sub class 7.2.

Group I, claims 1 - 21, 29 - 31, and 47, drawn to an isolated polypeptide, a pharmaceutical composition comprising said polypeptide, and a method of treatment using said polypeptide classified in class 530 subclass 350, are elected, with traverse.

As a traverse, it is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. MPEP § 803. Second, searching the additional inventions must constitute an undue burden on the examiner if

restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application "[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions." *Id.*

The Office Action fails to show how searching Groups I and II would present any undue or serious burden upon the Examiner.

In particular, it is noted that the Office Action states that "[i]nventions I and II are related as product and process of use" (*Office Action*, pg. 2). Based upon this characterization, search and examination of the elected Group I claims directed to the product (i.e., polypeptide) necessarily encompasses searching processes of using the polypeptides of the Group I claims. Based upon the search of the Group II use claims resulting from the search of the Group I product claims, the Office Action fails to establish how there is any undue burden on the Examiner in searching and examining all of the claims of Groups I and II.

Furthermore, claims 34 - 43 are method claims that contain the recitations of product claims within claims 1 - 21, 29 - 31, and 47. Thus, claims 34 - 43 are subject to rejoinder. Applicants respectfully request that claims 34 - 43, directed to methods of using the product of claims 1 - 21, 29 - 31, and 47, be rejoined into this application at this time, or at the time claims 1 - 21, 29 - 31, and 47 are indicated affirmatively to be allowable, pursuant to MPEP 821.04. That is, in accordance with MPEP 821.04, claims 34 - 43 can be rejoined into this application, and Applicants reserve a right of and request rejoinder. *See also* February 28, 1996 "Guideline on Treatment of Product and Process Claims ...", published at 1184 TMOG 86 (March 26, 1996), under which non-elected use or method claims may be rejoined into an application upon allowance of a product claim upon which the use or method claims depend or which contain the same recitation as the use or method claims.

Thus, there is no serious or undue burden on the Examiner in searching and examining together in this application claims 1 - 21, 29 - 31, and 47 and 34 - 43, or claims of Groups I and II, respectively. Indeed, search and examination of claims 1 - 21, 29 - 31, and 47 and 34 - 43 in this application, or rejoinder of Groups I and II, is mandated by the MPEP. Therefore, restriction between Groups I and II or a failure to search and examine claims 1 - 21, 29 - 31, and 47 and 34 - 43 is not warranted.

Moreover, the description of uses given in the Office Action, it is respectfully submitted, are "throw away," "insubstantial" or "nonspecific" and cannot be a basis for restriction. Specifically, the Office Action asserts uses such as a "diagnostic use" or use "as an antigen" (*Office Action* at 2, point 2). These general statement of use are considered "throw away," "insubstantial," or "nonspecific" uses; *see* the "Revised Utility Examination Guidelines" published on December 21, 1999 in the *Federal Register*, Vol. 64, Number 244. Under these new utility guidelines, a claimed invention will not be rejected for a lack of utility if the invention is "useful for any particular practical purpose (i.e., it has 'specific and substantial utility')." An example of a "throw away" use given in the revised guidelines is "the use of a complex invention as landfill." A copy of an article from Nature Biotechnology, 18:349-50 (March 2000) on the new utility guidelines is attached for the Examiner's convenience.

The claimed polypeptides have specific and substantial utility as required by the "Revised Utility Examination Guidelines" and as disclosed in the specification. The claimed uses (claims 34 – 43) encompass the claimed polypeptides (claims 1 - 21, 29 - 31, and 47); and thus, Groups I and II must be searched and examined in this application.

In addition, it is noted that under the PCT Rules, Groups I and II have Unity of Invention. More in particular, Example 1 of Annex B Part 2 of the PCT Administrative Instructions (Appendix AI of the MPEP, pg. AI-39) provides:

> Claim 1: A method of manufacturing chemical substance X.
> Claim 2: Substance X.
> Claim 3: The use of substance X as an insecticide.
>
> Unity exists between claims 1, 2 and 3. The special technical feature common to all the claims is substance X.

Accordingly, as in Example 1 above, there is Unity of Invention between the product claim, claim 2, and the use claim, claim 3; so Therefore, there is likewise Unity of Invention between Groups I (product claims) and II (use claims) in issue in this application. Therefore, restriction is improper between Groups I and II because the criteria for restriction have not been met, as evidenced by the cited Unity of Invention example.

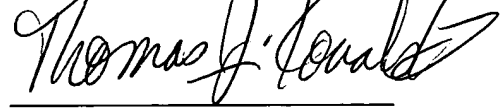
In further traverse of the restriction requirement, it is respectfully noted that the restriction requirement of the present Office Action is a re-restriction of previously elected Group I. In Paper No. 7, filed on November 15, 1999, Applicants' elected with traverse Group I (from Groups I, II and III) which encompasses claims 1-21, 29-31, 34-43 and 47. The re-restriction of this Office Action places an even greater burden on Applicants, the public, and the PTO.

The first restriction requirement called upon Applicants to prosecute three (3) patent applications - the present application and two (2) divisionals - and pay the fees therefor (including post-issuance fees such as maintenance fees and attorney fees, *inter alia*). Now, the re-restriction requires the Applicants to prosecute an additional application - in total four applications. This is an unfair and serious burden upon Applicants.

Accordingly, the restriction requirement is improper and must be reconsidered and withdrawn because: (1) there has been no showing of serious or undue burden (as required by MPEP 803) in searching and examining the Groups together and there can be no serious or undue burden in searching and examining Groups I and II because Group II is subject to rejoinder with the Group I claims under MPEP 821.04 and there is Utility of Invention between Groups I and II; (2) the claims of Groups I and II are subject to rejoinder under MPEP 821.04; (3) there is Utility of Invention between Groups I and II; (4) the restriction requirement is based on assertions of utilities that if set forth in a patent application would be considered "throw away" utilities, such that the allegations in the Office Action, it is respectfully submitted, are baseless; and (5), the restriction requirement, if maintained, places an unfair burden on Applicants.

Reconsideration and withdrawal of the restriction requirement and prompt examination of all of the claims of Groups I and II, on the merits, are respectfully requested.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

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PATENTS

Analyzing the USPTO's revised utility guidelines

Under the new guidelines, Section 101 "utility" rejections may make a comeback.

Thomas J. Kowalski

On December 21, 1999, the United States Patent and Trademark Office issued two new directives: "Revised Utility Examination Guidelines" and "Revised Interim Guidelines for Examination of Patent Applications under 35 USC §112, paragraph 1 'Written Description' Requirement." The intent was to streamline the patent prosecution process, but it is possible that in regard to biotechnology applications these guidelines may lead to unforeseen complications. In this, the first of two articles, we will examine the new Utility Guidelines. Next month, the revised Written Description Guidelines will be discussed.

The US Patent Law contains a "utility" requirement; that is, an invention must be useful[1]. Further, the US Patent Law provides that a patent specification must contain "a written description of the invention, and...the manner and process of making and using it, in...full, clear, concise and exact terms to enable" the skilled artisan "to make and use" it[2]. That is, the law has separate "written description" and "enablement" requirements[3]. The "use" prong of Section 112, first paragraph, incorporates the Section 101 requirement that a patent specification disclose a practical utility for an invention[4].

Thus, if a patent application fails to disclose how to use an invention, a US Patent Examiner can issue rejections under Sections 112 and 101. Indeed, in the late 1980s and early 1990s, there is some justification for stating that the biotechnology examining group of the USPTO issued lack of utility rejections under Section 101 that resulted in protracted patent prosecution, delays in the issuance of patents, and undue expense to applicants[5].

For example, a patent could be rejected based on Section 112 for insufficient written description and lack of enablement (for instance, because the invention was, in the examiner's view, unpredictable), and at the same time rejected as unpatentable because it was anticipated or obvious. Hence, applicants suffered "a classic Catch-22 situation."[5]

The Biotechnology Industry Organization (BIO) presented the situation to the USPTO and in response the USPTO published draft "utility" guidelines, and ultimately, in 1995, issued "Utility Examination Guidelines"[6]. Those 1995 Utility Guidelines instructed examiners that "[i]f the applicant has asserted that the claimed invention is *useful for any particular purpose* (i.e., a 'specific utility') and that assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility" (emphasis added). As a result, the problem of the "lack of utility" rejections under Section 101 was addressed because the threshold requirement for utility was minimal. However, with respect to certain biotech inventions, such as expressed sequence tags (ESTs), the ability to assert a utility "for any particular purpose" may have been thought by some to be too minimal a standard[7]. In view of this, the USPTO revised the 1995 Utility Examination Guidelines and issued the December 1999 "Revised Utility Examination Guidelines".

The latest changes

The newly issued Revised Utility Guidelines instruct examiners that "[i]f the applicant has asserted that the claimed invention is *useful for any particular practical purpose* (i.e., it has a 'specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility" (emphasis added). They also state that a claimed invention "must have a specific and substantial utility" that "excludes 'throw-away,' 'insubstantial' or 'non-specific' utilities" to satisfy the utility requirement of Section 101.

As an example of a "throw-away," "insubstantial" or "non-specific" utility, the new guidelines cite "the use of a complex invention as landfill." Clearly, the requirement for "a specific and substantial utility" will have an impact on biotech patent applications, especially those relating to nucleic acid molecules such as ESTs. Thus, patent applicants and practitioners should expect Section 101 and 112 rejections as a result of the new Utility Guidelines.

It should be noted that the new guidelines do appear to be an attempt to apply the case law. In particular, the Supreme Court, in *Brenner v. Manson*[8], set forth the requirements that a patent application contain a disclosure of "specific utility" and "substantial utility." *Manson* involved a claim to a process for preparing a steroid. Manson's patent application was rejected for failing to disclose a utility for this chemical compound, and Manson attempted to cure this omission by reference to an article that disclosed that steroids of the class to which the compound in question belonged were being screened for possible tumor-inhibiting activity. The Court upheld the rejection, stating that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing" and that "a patent is not a hunting license" because the "patent system must be related to the world of commerce rather than to the realm of philosophy."

Thereafter, in *In re Kirk*[9], the Court of Customs and Patent Appeals, predecessor to the Federal Circuit, held that a patent application directed to certain steroid compounds failed under Sections 101 and 112 because the utilities asserted were "biological activity" and "biological properties". The *Kirk* court held that "specific utility" is required under Section 101.

Thus, under the new Utility Guidelines the USPTO will be looking for "specific utility" and "substantial utility". With respect to DNA fragments or ESTs, the USPTO will be looking for a utility particular to the DNA fragment or EST that exists in a real-world context. For instance, a patent application containing a claim to a DNA fragment or EST with a disclosure that the DNA fragment or EST is useful as "a probe" will likely generate the examiner questioning the ultimate utility, namely: A probe for what?

In other words, a general statement of utility as "a probe" will likely be insufficient to satisfy the utility requirement as that statement will be considered a "throw-away utility," akin to the "biological activity" and "biological properties" rejected in *Kirk*.

However, if the DNA fragment or EST is disclosed as having the utility of mapping to a particular location in a genome, then the DNA fragment or EST will likely have sufficient utility because the utility is both specific (mapping to a particular location of a genome) and substantial (mapping to a particular location of a genome can have real-world applications).

A patent application containing a claim to a DNA fragment or EST can also assert that the utility of the claimed DNA fragment or EST is that it is a portion of an open reading frame encoding a particular protein. Such a utility assertion can be based on an analysis that shows that the claimed DNA fragment or EST is similar to the open reading frame of a known gene that encodes a known protein. However, this utility assertion, it is submitted, may generate yet still different inquiries.

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One utility inquiry as to the claimed DNA fragment or EST may be whether it is similar to any open reading frames of other known genes that encode other known proteins. If the claimed DNA fragment or EST is significantly similar to both the open reading frame of the known gene and another known gene, then a possible utility question may exist if it may be reasonably asserted that the skilled artisan does not or would not know which open reading frame may be encoded by the claimed DNA fragment or EST.

If the claimed DNA fragment or EST is not significantly similar to an open reading frame of another known gene, the claimed DNA fragment or EST may have utility but still trigger further inquiries. In *Manson*, the claimed process in issue indeed produced a steroid, but that fact, namely that a compound was indeed the result of the claimed process, did not end the utility inquiry. The inquiry in *Manson* was the utility of the compound that resulted from the process. Ultimately, the application was rejected because that compound failed to have specific and substantial utility in a real-world—not just a potential use-testing philosophical—context.

Likewise, it may be insufficient to assert that the claimed DNA fragment or EST is a portion of an open reading frame encoding a particular protein based on an analysis that shows that the claimed DNA fragment or EST is similar to the open reading frame of a known gene that encodes a known protein—even if the claimed DNA fragment or EST is not significantly similar to an open reading frame of another known gene as viewed by a skilled artisan.

For instance, if the known protein has specific and substantial utility, then the claimed DNA fragment or EST should have utility. An example of a protein having a specific and substantial utility is an antigenic protein of a pathogen that is useful in eliciting an immunological response. Hence, the protein is useful in generating that response and antibodies from that response, and the protein or antibodies can be useful in kits or assays for detection of the pathogen. But, an examiner may question whether the utility for the protein is a mere "throw-away" utility or a utility that is not specific and substantial.

Consider that the protein is a receptor. The claimed DNA fragment or EST may thus be useful for determining whether that receptor is present (e.g., through determining if a cell contains a DNA fragment or EST, such as through a hybridization analysis) or for generating molecules that may block that receptor (e.g., molecules that bind to the receptor). If that receptor is a known receptor found only on specific cells, then that which is expressed and the claimed DNA fragment or EST can have specific and substantial utility. However, if the receptor is found on every cell, then a question may exist as to the utility of the claimed DNA fragment or EST and that which is expressed. The receptor may lack utility and so too the claimed DNA fragment or EST.

Considering another type of invention involving DNA, a possible utility issue can arise with respect to a single nucleotide polymorphism (SNP), a single-base difference in a DNA sequence among individuals. If the asserted utility of the SNP is in the diagnosis of a particular disease, the issue may be whether there is indeed a causal relationship between the genetic variation and the disease; that is, whether the variation indeed causes the disease. However, this possible "utility" issue may be addressed if the patent specification shows that there is indeed a causal relationship between the variation and disease.

Possible consequences

The new Utility Guidelines direct that claims are to be rejected under both Section 101 and Section 112 if there is a lack of utility. Thus, Section 101 and 112 rejections may again become numerous. In regard to such rejections, it is important to remember that the initial burden is on the USPTO and the examiner to search and determine if assertions of utility in a patent application are credible and to use evidence or technical reasoning to challenge specific assertions. If the examiner makes a *prima facie* showing of no specific and substantial credible utility, the applicant bears the burden of rebutting it through claim amendment, reasoning or arguments, and/or evidence (e.g., declaration(s), printed publication(s)), that rebut the basis or logic of the examiner's *prima facie* showing. Such rejections can only be maintained if the totality of the record continues to show that the asserted utility is not specific, substantial and credible.

It also is important to consider that the new Utility Guidelines and the possible comeback of Section 101 and 112 utility issues may give rise to other effects. For instance, a patent application can only obtain the benefit of an earlier patent application if the earlier patent application discloses the claimed invention in accordance with Section 112[10]. An examiner may deny an applicant the benefit of an earlier application, such as an earlier foreign priority application, or an earlier US application (e.g., when the latter application is a continuation-in-part of the earlier application), if the earlier application fails to contain a specific and substantial credible utility for the claimed subject matter of the later application.

In addition to these Section 101 and 112 rejections making a comeback in patent prosecution, in court cases more litigants may raise the lack of specific and substantial credible utility in earlier application(s) in the lineage of the contested patent to attempt to deprive the contested patent of a filing date and invalidate the patent. For example, a litigation may hinge on a failure of an earlier application to comply with Sections 112 and 101 and an argument of anticipation or obviousness based on the publication of the priority application or a corresponding foreign application.

While it is not likely that the new Utility Guidelines will bring back in full force the "utility" problems that the biotechnology industry faced in the late 1980s and early 1990s, the patent landscape has been somewhat reshaped because Section 101 and 112 "utility" issues will now be raised. Patent applicants and professionals should tread differently on that landscape.

Acknowledgments

The opinions expressed herein are personal opinions of the author, and are not to be considered opinions of Frommer Lawrence & Haug LLP or any of the firm's clients. The author gratefully acknowledges the assistance of Elizabeth Pearce.

1. 35 USC §101.
2. 35 USC §112, first paragraph.
3. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991).
4. See *In re Cortright*, 49 USPQ2d 1464 (Fed. Cir. 1999).
5. See *Maximizing AIDS Drug Research by the Biotechnology Industry: Presentations of the Biotechnology Industry Organization to the Joint Meeting of the Public/Private Issues and Drug Development Subcommittees of the National Task Force on AIDS Drug Development* (April 25, 1995); *Cf. BIO News* 12/95, Looking Ahead ("The new Patent and Trademark Office Utility Guidelines, adopted by the PTO this year, are expected to save millions in legal fees"). Citing the 234-page agenda of reforms entitled *Critical Synergy: the Biotechnology Industry and Intellectual Property Protection* presented at an October 17, 1994, hearing regarding patent issues of concern to the biotechnology industry as identifying as one of the "key issues as the consideration by the PTO of the 'utility' of a biotechnology invention," noting "an unfortunate trend at the PTO toward requiring human clinical data to demonstrate utility" and damage resulting therefrom to "the small biotechnology company because it often must find corporate partners to fund clinical development which is very expensive" but "[w]ithout a clear patent position it can be difficult to recruit a partner."
6. 60 FR 36,263; 1177 OG 146 (July 14, 1995).
7. See 64 FR 71,428 (December 21, 1999) (The USPTO, with respect to the Interim Written Description Guidelines, 63 FR 32,639 (June 15, 1998), issued "The Extension of Comment Period and Notice of Hearing," 63 FR 50887 (September 23, 1998) and 1214 O.G. 180 (September 29, 1998), asking for comments regarding the patentability of ESTs); many respondents asserted that ESTs lacked the requisite utility to satisfy the US Patent Law; and, "[i]n view of comments and testimony with respect to ESTs and the enablement and utility requirements, the [USPTO]...revis[ed] the Utility Guidelines as published at 60 FR 36263 (July 14, 1995)"; see also *Letter of Carl Feldbaum, President, BIO, to The Honorable Bruce Lehman, Commissioner, USPTO* (January 26, 1998) (Stating: "We understand some EST applications will...provide the barest minimal disclosure that merely speculates EST utilities that would be true of most or all ESTs....[W]e request the PTO to publish for comment the examination guidelines regarding the patenting of ESTs, preferably with clear examples of the types of disclosure that will be sufficient for particular claim scope." And, "anticipat[ing] a similar convergence of opinion will occur in regard to single nucleotide polymorphisms (SNPs).").
8. 383 US 519-534-35, 148 USPQ 689-95 (1966). *Accord In re Ziegler*, 992 F.2d 1197, 1201, 26 USPQ2d 1600, 1603 (Fed. Cir. 1996) (requiring disclosure of specific and substantial or practical utility as a condition for satisfying requirement of §101).
9. 153 USPQ 48 (CCPA 1967).
10. See, e.g., 35 USC §§119, 120.